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REMARKS

In the Office Action pending claims 22-39 were rejected under by the Examiner.

Herein independent claims 22, 27 and 29 are amended, dependent claim 37 is amended, and no new claims are added, so claims 22-39 are pending examination on the merits.

Applicants herewith present a paragraph from page seven of the application as filed wherein the serial number of the co-pending application is filled-in.

Applicants respectfully request entry and favorable consideration of the amendments and remarks presented herewith.

Claim Rejection Under 35 U.S.C. §112

Claims 22-39 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Specifically, the Examiner alleges that the "range" of one of an intrinsically-activate heart rate and an evoked-activation heart rate.

Applicant asserts that the application as filed expressly and inherently includes the recited claim language. For example, at the paragraph bridging pages 8-9 the following support can be found for the notion of a range of heart rate stimulation rates in the presence of electromagnetic interference:

Accordingly, if the last spontaneous or stimulated heart rate was 80 bpm for the patient 107 prior to the detection of the presence of the magnetic field, the CPU 305 may stimulate the heart to a rate of 88 bpm (i.e., 8 bpm higher or 10% higher than the patient's heart rate prior to the magnetic field being detected). It will be appreciated, however, that the predetermined incremental factor may be a higher or lower percentage of the previously stored spontaneous or stimulated heart rate. It will further be appreciated that the predetermined incremental factor, as opposed to being a function of the patient's stored spontaneous or stimulated heart rate, may be a fixed value, such as 10 bpm, for example, that is added to the last stored spontaneous or stimulated heart rate. Of

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course, it will be appreciated that the fixed value may be higher or lower than the example provided. (emphasis added.)

Furthermore, at the end of the first full paragraph on page 11, the following support can be found for the claimed limitation:

In accordance with the illustrated embodiment, the predetermined incremental factor may be a percentage of the stored spontaneous or stimulated rate, such as 10%, for example. It will further be appreciated that the predetermined incremental factor may be a fixed value of 10 bpm, for example, to be added to the last retrieved spontaneous or stimulated heart rate to then become the new stimulation rate of the implantable device 105

Applicant notes that if the stored spontaneous or stimulated rate is increased by a fixed value of 10 bpm then depending on whether the underlying rate varies from 50 bpm to 100 bpm, a "range" of increases occurs. That is, at 50 bpm the increase equals a 20% increased stimulation rate while at 100 the increase equals 10%. Since a patient's heart rate can vary over a large range the application supports claim limitations including a "range."

Nevertheless, Applicant herewith amends the independent claims to delete the reference to the "range" and respectfully suggests that the rejection has been rendered moot and should be withdrawn.

Claim Rejections Under 35 U.S.C. §102/§103

Claims 22-39 stand rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, rendered obvious over EP 0931566 to Vock (Vock).

Applicants respectfully traverse the rejections as enumerated hereinbelow.

"A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim."
Trintec Indus. Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597, 1599 (Fed. Cir. 2002).
"Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." Id.

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In view of the differences between the claimed subject matter and the applied references identified above, Applicants respectfully assert that the rejections must be withdrawn. For example, nothing in Vock suggests or describes use of prior intrinsic or evoke heart rate data and using such data to set a new or different heart rate during exposure to supra-threshold high frequency (HF) radiation.

In connection with combining references to support an assertion of obviousness, it is well established that the Examiner bears the burden of establishing a *prima facie* case of obviousness. In re Oetiker, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention. In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A *prima facie* case of obviousness is established only when this burden is met.

The burden is still on the Examiner even when the Examiner relies upon a single reference. "Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." In re Kotzab, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000).

In the case of In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit stated: "This factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." *Id.* at 1434. Determination of patentability must be based on evidence, *id.* at 1434, and the Examiner provided none: no references pertaining to aggregation or averaging were cited, no official notice was taken, no evidence of any kind was presented. The Examiner's failure to present an evidentiary basis for the decision is clearly a legal error. *Id.* Assertions such as "common knowledge and common sense," even if assumed to derive from the Examiner's expertise, are not evidence, and conclusory statements do not fulfill the Examiner's obligation to make an

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evidentiary record. Id. at 1434-35; In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

If indeed the elements were known in the art, then the Examiner ought to present evidence to support that conclusion. In re Lee, 61 USPQ2d at 1435 (“[W]hen they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record.”). The failure to do so renders the Examiner’s rejection arbitrary, capricious and unreasonable. See id. at 1434. The Examiner may not arbitrarily, capriciously and unreasonably deny a claim by a mere declaration of obviousness without a supporting evidentiary record.

The Examiner presented no evidence of any suggestion or motivation to modify the Vock techniques to arrive at the claimed invention. Nor has the Examiner presented any evidence that the recited elements are known in the art.

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicant’s claims 22-39 under 35 U.S.C. §102(b)/§103(a). Withdrawal of this ground of rejection is hereby earnestly and respectfully requested.

Applicant respectfully asserts that Vock fails to teach or describe the limitations now recited in the pending claims including implementing an upper and a lower stimulation rate during operation of the “HF-interference pacing mode.”

CONCLUSION


Applicant respectfully asserts that all pending claims 22-39 of the present application are now in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

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Please charge any additional fees or credit any overpayment to deposit account number 13-2546. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Respectfully submitted,

Date: 27 June '05


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